

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER POR PATENTS PO Box (430) Alexandria, Virginia 22313-1450 www.orupo.gov

10/527,500	03/11/2005			
	03/11/2003	Jesus G Valenzuela	4239-66903-02	9994
36218 01/07/2009 KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET			EXAMINER	
			ARCHIE, NINA	
SUITE #1600 PORTLAND, OR	R 97204-2988		ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE 01/07/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/527,500 VALENZUELA ET AL. Office Action Summary Examiner Art Unit Nina A. Archie 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 29 September 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 2-5.25.27-33.35.36 and 80-88 is/are pending in the application. 4a) Of the above claim(s) 27-33.35.36 and 82-88 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 2-4.25 and 81 is/are rejected. 7) Claim(s) 5 and 80 is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

PTOL-326 (Rev. 08-06)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 9/18/2008.

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

Application/Control Number: 10/527,500 Page 2

Art Unit: 1645

DETAILED ACTION

This Office is responsive to Applicant's amendment and response filed 9-29-08.
 Claims 2, 5, 25, have been amended. Claims 1, 6-24, 26, 34, and 37-79 have been cancelled. Claims 27-33, 35-36, 82-89 have been withdrawn from consideration. Claims 2-5, 25, 80-81 are under examination.

Information Disclosure Statement

The information disclosure statement filed on 9/18/2008 has been considered.
 An Initialed copy is enclosed.

Rejections Withdrawn

- In view of the Applicant's amendment and remark following rejections are withdrawn.
- Rejection of claims 5, 25, and 81 under 35 U.S.C. 112, first paragraph is withdrawn in light of applicant's amendment of the claims.
- Rejection of claims 5-6, 77-79 under 35 U.S.C. 102(b) is withdrawn in light of applicant's amendment of the claims and cancellation of claims.

Rejection Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 2 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as

Art Unit: 1645

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons set forth in the previous office action.

Applicant arguments:

Claims 2 and 25 continue to be rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the invention at the time the application was filed. Claim 6 is canceled, rendering the rejection of this claim moot. Applicants traverse this rejection as it applies to claims 2, 5, and 25.

Solely to advance prosecution in this case, claim 2 is amended to be directed to "an amino acid sequence set forth as SEQ ID NO: 11." In addition, claim 5 is amended to be directed to an "immunogenic fragment..., wherein the immunogenic fragment comprises at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11, that specifically binds to an antibody that specifically binds the amino acid sequence set forth as SEQ ID NO: 11." Support for the amendment of claim 5 can be found in the specification at least at page 36, lines 5-7.

As established in Ex parte Parks, "adequate description under the first paragraph

of 35 U.S.C. 112 <u>does not require literal support</u> for the claimed invention

Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed" Exparte Parks, 30 USPQ2d 1234, 1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that "[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. See Hybritech Inc. v.

MonoclonalAntibodies, Inc., 802 F.2d at 1384,231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g. Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116; Martin v. Johnson, 454 F.2d 746, 751,172 USPQ 391,395

Art Unit: 1645

(CCPA 1972) (stating "description need not be in ipsis verbis [i.e., "in the same words"] to be sufficient")."

In the current instance, Applicants had possession of the peptide sequence set forth in SEQ ID NO: 11 and immunogenic fragments comprising at least fifteen consecutive amino acids of SEQ ID NO: 11 (for example, at page 36, lines 5-7). In addition, it was well known to those of skill in the art at the time the application was filed how to identify immunogenic epitopes of known sequences. For example, MHC binding peptide databases, such as the ProPred database

(http://www.imtech.res.in/raohava/propred), were available at the time the application

(http://www.imtech.res.in/raghava/propred), were available at the time the application was filed (Singh and Raghava, Bioinformatics, 17(12): 1236-1237, 2001). ProPred is a graphical web tool which can predict which regions of a known antigenic protein sequence binds class II MHC molecules and this database could have been used to identify immunogenic epitopes in polypeptide fragments that are "at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11". Thus, Applicants submit that a person of ordinary skill would have envisioned the claimed genus of immunogenic fragments, given the knowledge and level of skill in the art at the time the application was filed, the teachings of the specification, and the provision of SEQ ID NO: 11 itself.

In light of the above arguments and amendments, Applicants submit that claims 2 and 5 are sufficiently described by the specification and request that the rejection of these claims under 35 U.S.C. § 112, first paragraph, be withdrawn. Claim 25 depends from amended claim 2, and incorporates all the limitations thereof. In light of the above amendments, Applicants respectfully request that this rejection of claims 2, 5, 6, and 25 be withdrawn.

Examiner's Response to Applicant's Arguments:

Examiner accepts that the claims have been amended. Examiner accepts that the original disclosure clearly conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed.

Applicants Assertion also contemplated and provided explicit written description of polyoeptides comprising an amino acid sequence set forth as SEQ ID NO: 11. Claim

Art Unit: 1645

2 is drawn to a substantially purified salivary P. ariasi polypeptide, wherein the polypeptide comprises: a) an amino acid sequence set forth as SEQ ID NO: 11; b) a conservative variant of the amino acid sequence set forth as SEQ ID NO: 11; or c) an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11, that specifically binds to an antibody that specifically binds the amino acid sequence set forth as SEQ ID NO: 11, wherein administration of the polypeptide to a subject produces an immune response to P. ariasi. Examiner interprets claim 2 as set forth supra in a) as any amino acid sequence shown in SEQ ID NO: 11. Furthermore, Examiner interprets an amino acid sequence set forth as SEQ ID NO: 11 as any amino sequence in the sequence of SEQ ID NO: 11. Thus claim 2, states, a) a polypeptide comprises an amino acid sequence set forth as SEQ ID NO: 11, b) a conservative variants of the amino acid sequence as set forth as SEQ ID NO: 11, c) an immunogenic fragments comprising at least fifteen consecutive amino acids of SEQ ID NO: 11.

The specification, however, does not disclose distinguishing and identifying features of a representative member of the genus of the amino acids of SEQ ID NO: 11 to which the claims are drawn, such as a correlation between structure of the peptide and its recited function, so that the skilled artisan could immediately envision or recognize at least a substantial number of members of the claimed genus of antigens.

MPEP § 2163.02 states, "an objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See Vas-Cath, Inc.'v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the

Art Unit: 1645

invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (66 FR 1099-1111, January 5,2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (ld. at 1104).

The Guidelines further state, "[flor inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome and form immunoepitopes. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306).

No variant or amino acid sequence of SEQ ID NO: 11 described that has been modified without loss of immunogenicity. The specification provides no quidance as to

Application/Control Number: 10/527,500 Page 7

Art Unit: 1645

what amino acids can be changed and still provides a protective immune response as claimed. The specification lacks written description of any fragment or variant as claimed that provides the requisite functions of eliciting an immune response. The specification does not provide sufficient guidance as to which of the amino acids may be changed "without loss of immunogenicity" while structural or functional activity and specificity is retained. For example, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). The specification provides no quidance as to what amino acids can be changed and still provides a protective immune response. The specification lacks description of the specific structural features within an amino acid sequence set forth in SEQ ID NO: 11 correlate with protection from infection across the genus. Since the specification does not describe the genus of variants or amino acid sequence, the skilled artisan would not be able to readily envision what changes could be made and maintain the function of protection against infection. In view of the foregoing the specification lacks written description for an amino acid sequence of SEQ ID NO: 11.

Claim Rejections Maintained-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- The rejection of claims 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al WO9920644 Date April 29, 1999 are maintained as set forth in the previous office action.

Applicant arguments:

Art Unit: 1645

Jacobs et al. teaches an antigenic fragment of SEQ ID NO: 11 that is only eight amino acids long. As claims 2 and 5 are directed to immunogenic fragments comprising at least fifteen consecutive amino acids of SEQ ID NO: 11, Jacobs et al. does not and cannot anticipate claims 2 and 5. In light of the above arguments and amendments, Applicants respectfully request that this rejection of claims 2 and 5 be withdrawn.

Examiner's Response to Applicant's Arguments:

Examiner accepts that the claims have been amended and arguments. However, the argument is not deemed persuasive. Claim 2 is drawn to a substantially purified salivary P. ariasi polypeptide, wherein the polypeptide comprises: a) an amino acid sequence set forth as SEQ ID NO: 11; b) a conservative variant of the amino acid sequence set forth as SEQ ID NO: 11; or c) an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11, that specifically binds to an antibody that specifically binds the amino acid sequence set forth as SEQ ID NO: 11, wherein administration of the polypeptide to a subject produces an immune response to P. ariasi.

Examiner interprets claim 2 as set forth supra in a) as any amino acid sequence shown in SEQ ID NO: 11. Thus Jacobs et al teach an amino acid sequence show in SEQ ID NO: 11 of a polypeptide (see STIC RESULTS).

As outlined previously, claims 2, 6, and 77-79 are drawn to a substantially purified salivary *P. ariasi* polypeptide.

Jacobs et al teach an antigenic fragment of the polypeptide of SEQ ID NO: 11 (see STIC RESULTS).

New Ground Objections

6. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are added or canceled, the remaining claims must not be renumbered or miscounted. When new claims are presented, they must be numbered consecutively

Art Unit: 1645

beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Although claim 89 is withdrawn from consideration, Claim 89 is missing. Appropriate correction is advised.

New Ground Rejections Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 3-4, and 81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claim is drawn to a vast genus of the amino acid of SEQ ID NO: 11. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the

Art Unit: 1645

members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of the amino acid of SEQ ID NO: 11, applicant must also give a functional limitation of amino acid SEQ ID NO: 11.

Claim 3 is drawn to a substantially purified salivary P. ariasi polypeptide, wherein the polypeptide comprises an amino acid sequence set forth as SEQ ID NO: 11, or a conservative variant thereof, wherein administration of the polypeptide to a subject produces an immune response to P. ariasi. Examiner interprets claim 3 as set forth supra as any amino acid sequence shown in SEQ ID NO: 11. Furthermore, Examiner interprets an amino acid sequence set forth as SEQ ID NO: 11 as any amino sequence in the sequence of SEQ ID NO: 11. Thus claim 3, states, a polypeptide comprises an amino acid sequence set forth as SEQ ID NO: 11, or a conservative variant thereof.

The specification, however, does not disclose distinguishing and identifying features of a representative member of the genus of the amino acids of SEQ ID NO: 11 to which the claims are drawn, such as a correlation between structure of the peptide and its recited function, so that the skilled artisan could immediately envision or recognize at least a substantial number of members of the claimed genus of antigens.

MPEP § 2163.02 states, "an objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See Vas-Cath, Inc.'v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the

Art Unit: 1645

invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993)and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (66 FR 1099-1111, January 5,2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (ld. at 1104).

The Guidelines further state, "[flor inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome and form immunoepitopes. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306).

No variant or amino acid sequence of SEQ ID NO: 11 described that has been modified without loss of immunogenicity. The specification provides no quidance as to

Page 12

Application/Control Number: 10/527.500

Art Unit: 1645

what amino acids can be changed and still provides a protective immune response as claimed. The specification lacks written description of any fragment or variant as claimed that provides the requisite functions of eliciting an immune response. The specification does not provide sufficient guidance as to which of the amino acids may be changed "without loss of immunogenicity" while structural or functional activity and specificity is retained. For example, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). The specification provides no quidance as to what amino acids can be changed and still provides a protective immune response. The specification lacks description of the specific structural features within an amino acid sequence set forth in SEQ ID NO: 11 correlate with protection from infection across the genus. Since the specification does not describe the genus of variants or amino acid sequence, the skilled artisan would not be able to readily envision what changes could be made and maintain the function of protection against infection. In view of the foregoing the specification lacks written description for an amino acid sequence of SEQ ID NO: 11.

8. As to claims 2-4, the claims do not recite an article such as "the." The claims encompass any amino acid sequence shown in SEQ ID NO: 11 in step a). Amendment of the claims to add the word "The" would obviate this issue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1645

9. Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al WO9920644 Date April 29, 1999.

Claims 3-4 are drawn to a substantially purified salivary P. ariasi polypeptide.

Jacobs et al teach an amino acid sequence of SEQ ID NO: 11 of a polypeptide (see STIC RESULTS). Thus, Jacobs et al teach as set forth supra in a) as any amino acid sequence shown in SEQ ID NO: 11.

Status of the Claims

10. Claims 2-4, 25, 81 are rejected.

Claims 5 and 80 are objected as being dependent from a base claim.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should Application/Control Number: 10/527,500 Page 14

Art Unit: 1645

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/ Supervisory Patent Examiner, Art Unit 1645

Nina A Archie Examiner GAU 1645 REM 3B31